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10/734,670	12/11/2003	Richard S. Ginn	15997.4002	6280

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EXAMINER	
TYSON, MELANIE RUANO	

ART UNIT	PAPER NUMBER
3773	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,670	GINN, RICHARD S.	
	Examiner	Art Unit	
	MELANIE TYSON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the applicant's amendment received 08 July 2009. Claims 1-29 remain cancelled.

Response to Arguments

Applicant's arguments filed 08 July 2009, with respect to the rejection(s) of the claims by Schreck et al. have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of Oman et al. (see new rejection below).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 64, 98, and 99 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At the time the application was filed, the applicant failed to disclose the step of advancing the implantable device through specifically the inferior or superior vena cava to the heart. Therefore, the limitations are considered new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 recites the limitation "situating the implantable device...within a second piercing in **the portion of the second tissue flap overlapping the first tissue flap**" in the second paragraph. However, the first paragraph recites "at least a portion of the first tissue flap overlapping at least a portion of the second tissue flap" and thus the requirement of a portion of the second tissue flap overlapping the first tissue flap has not been recited in the claims. Therefore, there is insufficient antecedent basis for this limitation in the claim. Claims 31-106 are also rendered indefinite as depending directly or indirectly from claim 30.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 30, 31, 33-58, 60-63, 65-86, 95, and 101-106 are rejected under 35 U.S.C. 102(e) as being anticipated by Oman et al. (U.S. Patent No. 7,288,105 B2). Oman discloses a method for treating a patent foramen ovale (see entire document) comprising the steps of advancing an implantable device (30) through the vasculature of a subject within an elongate delivery apparatus (a catheter; for example, see column 9,

lines 25-27) and situating, engaging, and releasing the implantable device within piercings of overlapping first and second tissue flaps defining a tunnel (piercing is formed by the needle-like tips of the filament 40 of the implantable device which penetrate the tissue), wherein a first elongate portion of the device (end of 40 in left atrial chamber) engages the first tissue flap and is exposed in a second (left) atrial chamber, a second elongate portion of the device (end of 40 in left atrial chamber or vice versa - see claim 62) engages the second tissue flap and is exposed in a first (right) atrial chamber, an intermediate portion of the device lies between the first and second portions (see below for details on the composition on the first and second portions in which the intermediate portion lies between the defined boundaries), and the first and second elongate portions may be considered to be made up of a first end (passed through the tissue flap in chambers), intermediate region (portions within the tissue flaps), and second end (a portion of segment within the tunnel formed by the flaps and panel portion 32 or vice versa in which the first portion would comprise a portion lying substantially perpendicular to a longitudinal axis of a portion within the first piercing as recited in claim 42) all pivotally coupled in that the entire portion (40) is formed of a spring material and thus any portion may pivot relative to the other to retain the tissue flaps (for example, see Figure 24 for illustration). Oman further disclose the steps of externally imaging the implantable device having radiopaque markers (for example, see column 8, lines 50-64), deploying the biased device from the elongate delivery apparatus such that it transforms, pivots, or transitions to a retaining configuration (for example, see Figure 24 and column 9, lines 25-31), securing the

second portion to the device to retain the second portion against the second tissue flap (for example, see Figure 24), the second portion includes retaining arms or laterally extending members (opposing portions of panel 32 defined by support structure 36) capable of engaging and retaining the second tissue flap as they lie substantially in a plane parallel to the second tissue flap and thus may be considered "locking elements" that lockingly engages the filament (or wire "suture" 40), the device may comprise NITINOL or other shape memory material (for example, see column 8, lines 20-32), and the first portion (for example, portion 32 of the device) resides substantially flat against the first tissue flap in the retaining configuration (in order to fully contact the tissue; for example, see column 7, lines 39-42).

Regarding claims 45, 54-58, and 84, it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. Since these claims simply recite the use of a particular structure, the limitations are not entitled to weight in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 32, 64, and 98-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oman and Atkinson et al. (U.S. Patent No. 6,645,225 B1). Oman discloses the claimed invention except for the step of advancing the device through the inferior or superior vena cava, or through an artery, to the heart using specifically fluoroscopy imaging. Atkinson discloses a method of treating a patent foramen ovale (PFO) in the heart. Atkinson teaches the step of advancing the device through the inferior vena cava and into the right atrium of the heart utilizing fluoroscopy imaging to deploy the implantable device (for example, see column 4, lines 19-26). It would have been obvious to one having ordinary skill in the art at the time the invention was made to advance and image Oman's device as taught by Atkinson in order to easily and accurately deliver and deploy the device.

With further respect to claims 99 and 100, it is well known in the art that the superior vena cava and other arteries provide access to the right atrial chamber. The applicant has failed to disclose advancing the device through the superior vena cava or other arteries provides an advantage, is used for a particular purpose, or solves a stated problem and it appears the step of advancing the device through the inferior vena cava

to the right atrial chamber as taught by Atkinson would perform equally well. Since one having ordinary skill in the art could have advanced the device through the superior vena cavity or other arteries to the right atrial chamber and the applicant has not disclosed any benefit of doing so, such a modification would have been an obvious matter of design choice at the time of the invention.

Claims 87-94, 96, and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oman and Gainer (U.S. Patent No. 6,440,152 B1). Oman discloses the claimed invention except for the step of advancing the device through the elongate member with a distal end of an elongate pusher member having an actuator and gripping mechanism for gripping the device. Gainer discloses a method of treating a patent foramen ovale (PFO) in the heart. Gainer teaches the steps of advancing an elongate member (22) having an atraumatic distal tip to the heart and advancing the implantable device through the elongate member via pusher member (20) having gripping mechanism (28 which grips the eyelets of the implantable device) and inherently an actuator (for actuating the pushing function disclosed). It would have been obvious to one having ordinary skill in the art at the time the invention was made to advance the implantable device of Oman (having eyelets 46 for gripping Gainer's gripping mechanism 28) utilizing the deployment mechanism taught by Gainer. Doing so would enable proper deployment and placement of Oman's implantable device. With further respect to claims 96 and 97, it would have been obvious to one having ordinary skill in the art at the time the invention was made to also include radiopaque markers on the tubular member and pusher member in order to be able to visualize the location of

the two prior to deployment of the implantable device utilizing Oman's imaging techniques. Doing so would ensure the implantable device is deployed at the proper site.

Allowable Subject Matter

Claim 59 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest, in combination with other limitations in the base and intervening claims, the first and second tissue flaps are engaged such that the first flap is held in contact with the second tissue flap to close the tunnel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/
Examiner, Art Unit 3773
October 30, 2009